

Appln No. 10/715,221
Amdt date March 17, 2008
Reply to Office action of December 26, 2007

REMARKS/ARGUMENTS

Claims 24, 25, 31-46 and 50 are pending in the present application, of which claims 25, 35, 39, 41 and 43 have been withdrawn.

Claims 24, 31-34, 36-38, 45, 46, and 50 have been rejected under 35 U.S.C. 103 (a) over Swanson, et al. (US 5,582,609) in view of Myers (US 5,716,397). Claim 24 recites "wherein at least a portion of the forming element is configured to be removable after implantation of the elongate body within the coronary sinus." On page 3 of the Office action, the Examiner states the following:

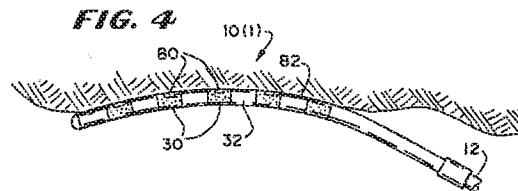
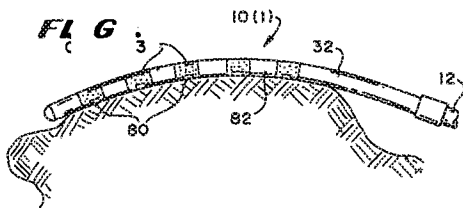
Swanson does not disclose at least a portion of the forming element being removable after implantation. Myers discloses an annuloplasty device with a forming element 28 that is removable upon implantation of the device in order to restore full flexibility to the device after implantation (col. 2, 11. 7-10). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Swanson with the removable forming element of Myers in order to restore full flexibility after the device is implanted as taught by Myers (col. 2, 11. 7-10).

Applicants traverse this rejection because combining the forming element of Myers with Swanson would render the device of Swanson unsatisfactory for its intended purpose. Furthermore, one of ordinary skill in the art would not have combined Myers with Swanson because such a combination would not provide any advantage to the device of Swanson.

Swanson et al. is directed to a system having curvilinear electrode elements for forming large lesions in body tissue. Referring to FIGS. 1 and 2, Swanson et al. discloses a flexible ablating element 10 that is carried by a catheter 12 with a handle 16. A steering mechanism 18 bends the ablating element 10 in two opposite directions by pulling two wires, which are right and left wires 24. *See also FIGS. 27 and 28.* "The wires 24 pass through the catheter body 12 and connect to the left and right sides of a resilient bendable wire or spring 26 (best shown in FIGS. 20 and 23) enclosed within a tube 28 inside the ablating element 10." *See col. 5, lines 44-47.* The ablating element 10 includes ablating electrodes that when

in contact with heart tissue form lesions at the contact area upon receiving ablating energy.
See for example, col. 8, line 60 to col. 9, line 39.

Also referring to FIGS. 3-6 of Swanson, of which FIGS. 3 and 4 are reproduced below, in order to steer the ablating element 10, conform the shape of the ablating element 10 to a tissue region, and maintain such a shape to thereby provide contact between the electrodes and tissue, an operator must bend the ablating element 10 with the pull wires 24. *See col. 6, lines 54-67.* Thus, the ablating element 10 is flexible while the pull wires 24 along with the spring 26 provide steering and resilient bendability for the ablating element 10.



Referring to FIGS. 4 and 5 of Myers, which are reproduced below, Myers discloses an annuloplasty ring having a rectangular inner core 12 of radio-opaque silicone rubber which is radially completely flexible so as to allow a surgeon to monitor the implant after surgery. The ring is implanted in the heart to prevent a heart valve annulus from being distended. The ring, which is constructed from cloth, is sutured to the valve annulus at locations 15. *See col. 2, lines 46-64.* Thus, the cloth prevents expansion of the valve annulus.

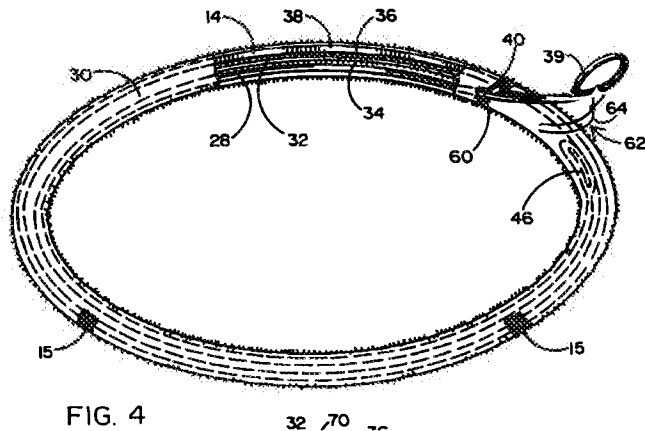
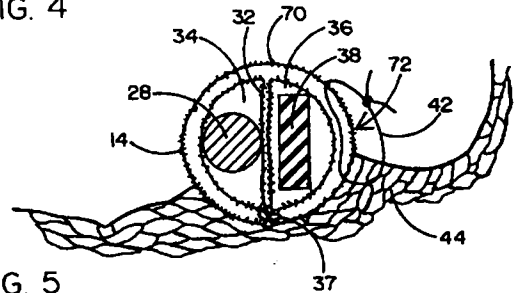


FIG. 4



In order to prevent the cloth from bunching or pleating when the implant sutures are tied off, the ring further includes a stiffener 28, which extends around the entire ring. The stiffener maintains the shape of the ring by keeping the cloth taut to prevent bunching or pleating when the cloth is being sutured to the valve annulus. (*See col. 3, lines 2-10*). After the ring is sutured to the valve annulus, the stiffener 28 is pulled out of the ring by a surgeon pulling on the grasping portion 39. (*See col. 3, lines 25-35*). Thus, the function of the stiffener 28 is to stiffen the ring for implantation in the valve annulus.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to "combine the device of Swanson with the removable forming element of Myers in order to restore full flexibility after the device is implanted as taught by Myers." Applicants submit that combining the stiffener 28 of Myers with Swanson would make the device of Swanson stiff, and therefore, unsatisfactory for its intended purpose. The ablating element 10 of Swanson has to be flexible so that a surgeon can steer the ablating element 10 to a desired area for forming lesions. Furthermore, as shown above by FIGS. 3 and 4 of Swanson, once the ablating element 10 reaches a desired area, the ablating element 10 has to be flexible so as to conform to the contour of the tissue. If the stiffener 28 of Myers is combined with the device of Swanson, the ablating element 10 of Swanson would become stiff. As a result, a surgeon would have difficulty bending the ablating element 10 to steer the ablating element to a desired location and conforming the shape

Appln No. 10/715,221
Amdt date March 17, 2008
Reply to Office action of December 26, 2007

of the ablating element 10 to the contour of the tissue at the desired location. Therefore, one of ordinary skill in the art would not combine the stiffener 28 of Myers with the ablating element 10 of Swanson because the combination would render the device of Swanson unsatisfactory for its intended purpose.

Furthermore, Applicants submit one of ordinary skill in the art would not have combined the stiffener 28 of Myers with the ablating element 10 of Swanson, because the device of Swanson would not gain any functional advantage from such a combination. As discussed above, the ablating element 10 of Swanson is flexible so as to be steerable and conforming to tissue contour. However, by using the wires 24 of the steering mechanism 18 and the resilient bendable wire or spring 26 (shown in FIGS. 20 and 23), a surgeon can selectively stiffen the ablating element 10 of Swanson. For example, as shown in FIG. 6 of Swanson, a surgeon can move the ablating element 10 to any of the two positions shown with the steering mechanism 18. Furthermore, the surgeon can maintain the positions by using the steering mechanism to maintain the tension in the wires 24. Accordingly, at any point during the operation of the ablating element 10, the surgeon can stiffen the ablating element 10 with the steering mechanism 18. Therefore, one of ordinary skill in the art would not have any motivation to combine the stiffener 28 of Myers with the device of Swanson, because such a combination would not provide any functional advantage to the device of Swanson.

For the foregoing reasons, Applicants submit that claims 24, 31-34, 36-38, 45, 46, and 50 are patentable over Swanson in view of Myers.

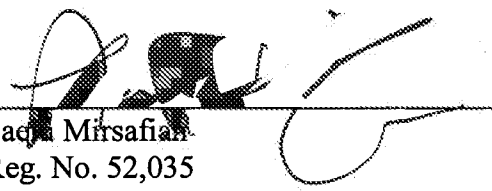
Claims 40, 42, 44, and 46 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson in view of Myers and further in view of Goldsteen (US 6,206,912). Because claim 24 is patentable over Swanson in view of Myers, Claims 40, 42, 44 and 46 are also patentable over Swanson in view of Myers and Goldsteen.

Based on the foregoing, Applicants respectfully request allowance of the claims.

Appln No. 10/715,221
Amdt date March 17, 2008
Reply to Office action of December 26, 2007

Respectfully submitted,
CHRISTIE, PARKER & HALE, LLP

By



Saeed Mirsafian
Reg. No. 52,035
626/795-9900

SM/mr

MIR IRV1112289.2-*03/17/08 11:04 AM